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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,800	11/06/2000	Thomas Strungmann	4271-29PUS	5697

7590 10/03/2003

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 10/03/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,800	STRUNGMANN, THOMAS	
	Examiner	Art Unit	
	Susan Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Continued Examination and Request for Extension of Time filed 05/05/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/05/03 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frangin et al. US 5,985,915.

Frangin teaches a patch for transdermal composition comprising active ingredients, excipient (column 6, lines 24-65), and at least one additional cardioactive

agent selected from the group consisting of diuretic, and angiotensin II, e.g., candesartan (column 8, lines 43-67).

Regarding to claims 18-22, the reference differs from the claimed invention by not teaching the specific form of candesartan or its' salts. However, it would have been prima facie obvious for one of the ordinary skill in this art to, by routine experimentation determine a suitable form of candesartan suitable for transdermal patch.

The examiner notes that Frangin is silent as to the teaching of diuretic or calcium blocker as a second therapeutic agent. However, Frangin teaches the active ingredients selected from benzofuran can be formulated in combination with one or more pharmaceutically vehicles (see abstract). Thus, it would have been obvious for one of the ordinary skill in this art to select more than one cardioactive agent, e.g. diuretic and angiotensin inhibitor, to obtain a transdermal patch containing candesartan.

Claims 16, 17, and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poss US 5,616,591, in view of Frangin et al.

Poss teaches a composition for transdermal patch comprising an angiotensin inhibitor agent in combination with a diuretic agent as a second compound (columns 7, lines 40 through column 8, lines 1-29). Poss does not suggest the use of a specific compound of angiotensin inhibitor.

Frangin teaches a transdermal patch composition comprising angiotensin inhibitor agent, e.g., candesartan (column 8, lines 66-67). Thus, it would have been prima facie obvious for one of the ordinary skill in the art to modify Poss's transdermal

patch using candesartan as an angiotensin agent in view of the teaching of Frangin. The reason for this modification is to obtain a transdermal patch containing candesartan useful for the treatment of heart diseases.

Claims 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poss and Frangin et al., in view of Jalonen et al. US 5,464,628.

Poss and Frangin are relied upon for the reasons stated above. The references are silent as to the teaching of the ingredients of a transdermal patch.

Jalonen teaches a pharmaceutical composition containing substituted imidazole to be administered transdermally (abstract). The transdermal patch comprises a an impermeable backing layer and an adhesive layer; or an impermeable backing layer, an adhesive layer, and a matrix layer; or a drug reservoir system (column 2, lines 36-64). The backing layer can be flexible or non-flexible materials: polyethylene, or polypropylene; the adhesive layer can be polysiloxanes, polyacrylates, or ethylene-vinyl acetate; and the matrix layer can be of natural or synthetic rubbers (column 3, lines 21-51). The composition further comprising carrier and penetration enhancers, e.g., polyethylene glycol, propylene glycol, isopropanol, ethanol, oil, or a mixture thereof (column 2, lines 65 through column 3, lines 1-20). Thus, it would have been prima facie obvious for one of the ordinary skill in this art to prepare the composition of Poss and Frangin in a transdermal patch in view of the teaching of Jalonen. The reason for this modification is to obtain a candesartan transdermal patch that will provide a high bioavailability of drug penetration.

Response to Arguments

Applicant's arguments filed 03/04/03 have been fully considered but they are not persuasive.

Applicant's argument regarding to Frangin cannot be an anticipatory reference is persuasive, and therefore, the 102(e) rejection has been withdrawn. Nonetheless, the examiner maintains the 103(a) rejection over Frangin, although applicant fails to argue the obvious rejection over Frangin et al. Applicant argues that Frangin does not disclose any example having a transdermal formulation comprising candesartan. However, Frangin is relied upon for the teaching within the four walls patent. Frangin cannot be limited to his best mode as describe or not describe in the examples. Frangin teaches his compositions can be administered through oral, sublingual, nasal, inhaled, parenteral, topical, rectal, and transdermal, wherein, a transdermal patch is even mentioned (column 6, lines 25-36). The active ingredients to be incorporated into Frangin's compositions including candesartan in combination with benzofuran derivatives (column 8, lines 34-67). Thus, it would have been obvious for one of ordinary skill in the art to optimize Frangin's compositions to obtain a transdermal patch comprising combination of active ingredients, including candesartan. It is noted that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant argues that not all therapeutically active substances are suitable for transdermal administration (cited Jalonen, column 2, lines 13-29), and therefore, any broad conclusion of obviousness is not warranted and the art specifically teaches away from such a broad conclusion. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Jalonen teaches a transdermal patch comprising active drugs, including, antihypertensive active agent for the treatment of hypertension (column 1, lines 41-50). Candesartan is a well known for the treatment of heart disease, and hypertension. Therefore, it is the position of the examiner that it would have been obvious for one of ordinary skill in the art to combine the teaching of Frangin and Jalonen since the references are teaching transdermal patch containing therapeutic agents, including antihypertensive agent.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nisato is cited as of interest for the teaching of transdermal composition comprising angiotensin II antagonist compound.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600